TRANSACTIONS GRANTED EARLY TERMINATION BETWEEN: 013095 AND 021095—Continued

Name of acquiring person, name of acquired person, name of acquired entity	PMN No.	Date terminated
Harbour Group Investments III, L.P., DelCorp Incorporated, DelCorp Incorporated	95–0901	02/01/95
Penn Virginia Corporation, United Meridian Corporation, UMC Petroleum Corporation	95–0903	02/01/95
Philipp Holzmann, A.G., Costain Group PLC, The Dolet Hills Mining Venture	95–0905	02/01/95
North Shore Regional, Health System, Huntington Hospital, Huntington Hospital	95–0822	02/03/95
Archer-Daniels-Midland Company, Archer-Daniels—Midland Company, Independent Soy Processors Company	95–0895	02/03/95
USF&G Corporation, Victoria Financial Corporation, Victoria Financial Corporation	95–0897	02/03/95
La-Z Boy Chair Company, England/Corsair, Inc., England/Corsair, Inc.	95–0912	02/03/95
Siemens Aktiengesellschaft, Pyramid Technology Corporation, Pyramid Technology Corporation	95–0913	02/03/95
Corporate Express, Inc., G. Lynn Shostack, Joyce International, Inc.	95–0926	02/03/95
HBE Corporation, Barclays PLC, Pawnee-Daytona Inc.	95–0965	02/03/95
Logicon, Inc., Harnischfeger Industries, Inc., Syscon Corporation	95–0920	02/06/95
Corning Incorporated, Corning BioPro Inc., Corning BioPro Inc	95–0928	02/06/95
United Healthcare Corporation, Luis A. Salgado Torres, Group Sales and Service of Puerto Rico, Inc.	95–0958	02/06/95
Molex Incorporated, Mod-Tap W Corp., Mod-Tap W Corp.	95–0886	02/07/95
Alma Energy Corp., Unocal Corporation, Union Oil Company of California	95–0932	02/07/95
The Horne Family Voting Trust, Anderson Family Trust, Anderson-Barrows Metals Corporation	95–0943	02/07/95
Pharmacia AB, Ms. Jacqueline Hoefer, Hoefer Scientific Instruments	95–0756	02/09/95
Mallinckrodt Group Inc., The Procter & Gamble Company, J. T. Baker Inc.	95–0737	02/10/95
Coats Viyella Plc, BACE Manufacturing, Inc., BACE Manufacturing, Inc.	95–0918	02/10/95
Ronald O. Perelman, Abex Inc., Abex Inc.	95–0929	02/10/95
The News Corporation Limited, SCS Communications, Inc., Westview Press, Inc.	95–0944	02/10/95
Ashland Oil, Inc., Mr. Ira L. Morris and Mrs. Betty Sue Morris, Waco Oil & Gas Co., Inc.	95–0949	02/10/95
Vincent J. Ryan, James F. Knott, National Business Archives, Inc.	95–0955	02/10/95
VIAG AG, AmeriQuest Technologies, Inc., AmeriQuest Technologies, Inc.	95–0956	02/10/95
Beverly Enterprises, Inc., Pharmacy Management Services, Inc., Pharmacy Management Services, Inc.	95–0960	02/10/95
Pennzoil Company, Limited Liability Company, Limited Liability Company	95–0961	02/10/95
The Brooklyn Union Gas Company, Limited Liability Company, Limited Liability Company	95–0962	02/10/95
Phillips-Van Heusen Corporation, Crystal Brands, Inc. (Debtor-In-Possession), Crystal Brands, Inc. (Debtor-In-Possession)	95–0963	02/10/95
Precision Castparts Corp., Columbus II Limited Partnership, Quamco, Inc.	95–0970	02/10/95
William Herbert Hunt Trust Estate, Texaco Inc., Texaco Exploration and Production Inc.	95–0978	02/10/95
National Gaming Corp., Part-A-Dice Gaming Corporation, Par-A-Dice Gaming Corporation	95–0980	02/10/95
Sonat Inc., Hardy Oil & Gas PLC (a Britishcompany), Hardy Holdings, Inc.	95–0993	02/10/95

FOR FURTHER INFORMATION CONTACT: Sandra M. Peay or Renee A. Horton, Contact Representatives, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room 303, Washington, D.C. 20580, (202) 326–3100.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 95–4396 Filed 2–22–95; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Availability of Draft U.S. Public Health Service Recommendations for HIV Counseling and Testing for Pregnant Women

AGENCY: Centers for Disease Control and Prevention (CDC), Public Health Service (PHS), Department of Health and Human Services.

ACTION: Notice of availability and request for comments.

SUMMARY: This notice announces the availability for review and comment of a draft document entitled ''U.S. Public Health Service Recommendations for HIV Counseling and Testing for Pregnant Women.'' The document was prepared by CDC staff in collaboration with other internal PHS and external consultants.

DATES: To ensure consideration, written comments on this draft document must be received on or before April 10, 1995.

ADDRESSES: Requests for copies of the draft recommendations must be submitted to the CDC National AIDS Clearinghouse, P.O. Box 6003, Rockville, MD 20849–6003, telephone (800) 458–5231. Written comments on the draft document should be sent by mail or facsimile to the Technical Information Activity, Division of HIV/AIDS, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Mailstop E–49, 1600 Clifton Road, NE., Atlanta, GA 30333, facsimile (404) 639–2007, for receipt by April 10, 1995.

FOR FURTHER INFORMATION CONTACT: Technical Information Activity, Division of HIV/AIDS, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Mailstop E–49, Atlanta, GA 30333.

SUPPLEMENTARY INFORMATION: In February 1994, the National Institutes of Health announced interim results from AIDS Clinical Trial Group (ACTG) protocol 076 indicating that zidovudine (ZDV) therapy administered to a select group of HIV-infected pregnant women and their newborns reduced the risk of perinatal HIV transmission by approximately two thirds. In April 1994, provisional recommendations for the use of ZDV therapy in HIV-infected pregnant women and their newborns were published. In June 1994, representatives from Federal and nonfederal health agencies and other organizations attended a meeting in Bethesda, Maryland, to discuss development of U.S. Public Health Service recommendations to prevent perinatal HIV transmission and the implications of those recommendations for HIV treatment, counseling, and HIV testing. In August 1994, the U.S. Public Health Service published recommendations for ZDV therapy to reduce the risk of perinatal transmission of HIV (also available from the CDC

National AIDS Clearinghouse, telephone (800) 458–5231).

The draft recommendations for HIV counseling and voluntary testing for pregnant women have been developed to provide a framework to enable pregnant women to know their HIV infection status; advise HIV-infected pregnant women of ways to prevent perinatal, sexual, and other transmission of HIV; facilitate appropriate follow up for HIV-infected women and their infants; and assist uninfected pregnant women in identifying methods to reduce their risk of acquiring HIV infection.

Dated: February 15, 1995.

Jack Jackson,

Acting Director, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95–4368 Filed 2–22–95; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 88N–0319]

Home Specimen Collection Kit Systems Intended for Human Immunodeficiency Virus (HIV–1 and/or HIV–2) Antibody Testing; Revisions to Previous Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is revising its previous guidance for the approval of home specimen collection kit systems intended for the detection of antibodies to Human Immunodeficiency Virus type 1 (HIV–1), that was published in the **Federal Register** of February 17, 1989, and July 30, 1990.

DATES: Submit written comments by April 10, 1995.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mary Gustafson, Center for Biologics Evaluation and Research (HFM–370), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–2012.

SUPPLEMENTARY INFORMATION:

I. Background

FDA announced in the **Federal Register** of February 17, 1989 (54 FR 7279), the scheduling of an open public meeting and invited written comments on blood collection kits and home test kits designed to detect HIV–1 antibody. The document listed five factors that the agency was applying to the review of applications for premarket approval of blood collection kits labeled for HIV–1 antibody testing. At that time, FDA believed that blood collection kits labeled for HIV-related testing should be restricted to professional use in a health care environment. On April 6, 1989, FDA held an open public meeting to obtain comments on the issues related to applications for premarket approval of blood collection kits labeled for HIV–1 antibody testing. Comments also were solicited on kits for home collection and home testing of blood for evidence of HIV–1 infection.

In the **Federal Register** of July 30, 1990 (55 FR 30982), FDA announced the availability of a letter to firms and individuals who previously had asked FDA about the potential marketing of blood collection kits labeled for HIV–1 testing. In that document, which included the full text of the letter, FDA indicated its willingness to accept investigational device exemptions (IDE's) and to review applications for blood collection kits for HIV–1 testing intended for home use, but did not revise the list of factors, previously set forth in the February 17, 1989, **Federal Register** (54 FR 7279) document, that the agency would consider in evaluating the safety and effectiveness of specimen collection kits.

In light of scientific and technological developments and the changing nature of the HIV epidemic, FDA announced in the **Federal Register** of June 9, 1994 (59 FR 29814), that the agenda for FDA's Blood Products Advisory Committee meeting, scheduled for June 21 and 22, 1994, would include a discussion of issues related to home specimen collection kits labeled for HIV antibody testing, and that the discussion would reexamine FDA's approach to evaluating the safety and effectiveness of such kits. More than 60 members of the public, including potential product sponsors, academicians, physicians, clergy, HIV counselors, and representatives of various interest groups, made public presentations before the Blood Products Advisory Committee prior to the committee's discussion of these issues. Most of the advisory committee members believed that the potential benefits of over-the-counter (OTC) home specimen collection kits outweighed the potential risks.

II. The Revision

In this document, FDA is revising the previous guidance for blood sample collection kits labeled for HIV antibody testing set forth in the February 17, 1989, **Federal Register** document and in the July 30, 1990, **Federal Register** document. This revised guidance addresses only OTC products intended for the home collection of specimens (including blood and non-blood based specimens) for HIV antibody testing (including HIV–1 and/or HIV–2), and supersedes prior guidance about such home specimen collection kits. This revised guidance does not address professional use specimen collection kits for HIV testing or kits for home testing of specimens for evidence of HIV infection.

After significant consideration, including discussion at two public meetings, FDA has concluded that OTC home specimen collection kit system for HIV testing may be approvable. Each premarket approval application (PMA) for an OTC home specimen collection kit system labeled for HIV–1 and/or HIV–2 antibody testing will be evaluated for safety and effectiveness based on the proposed intended use. In general, sponsors should include information on the following points:

(1) Appropriate preclinical studies and clinical trials conducted under an approved IDE should validate all technical aspects of the home specimen collection and testing system and demonstrate the reproducibility, sensitivity, and specificity of test results in comparison with an approved, professional use system for the collection and testing of blood or any other appropriately validated specimen. Field trials should be conducted in a population likely to resemble the intended market for the collection kit. Lay comprehension of the instructions and educational materials, the ability of individual consumers to accurately identify whether the test is applicable to them, adequacy of home collection and shipment of the specimen by consumers, the adequacy of pretest and post-test counseling, and the ability of consumers to take appropriate followup action when indicated should be addressed. Safe handling and transport of the specimen and safe disposal of potentially hazardous materials also should be demonstrated. Sponsors additionally should document adequate quality assurance related to product manufacture, testing of the specimen (including laboratory proficiency controls) in a laboratory that is in compliance with the Clinical Laboratories Improvement Act of 1988 (CLIA), maintenance of test records, and a system for reporting of adverse events or device failures.

(2) The testing for all specimens collected using the home specimen collection kits should include the use of